### 510(k) Summary of Safety and Effectiveness Prepared in accordance with 21 CFR Part 807.92

Section a):

1. Submitter:

Hitachi Aloka Medical Co., Ltd., 10 Fairfield Boulevard, Wallingford, CT 06492

Contact Person:

Angela Van Arsdale, RA/QA Mngr.,

Tel: (203)269-5088 Ext. 346, Fax: 203-269-6075

Date Prepared:

7/10/12

Device Name:

Prosound Alpha 7 Ver. 6.0 Diagnostic Ultrasound System

Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550, 90 IYN

Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90 ITX Ultrasonic Pulsed Echo Imaging System., 21 CFR 892.1560, 90 IYO

3. Substantially Equivalent devices: Aloka SSD- Alpha 7 Diagnostic Ultrasound System K072285 for probes and

system. Aloka SSD-5500 (K032875), Aloka Prosound F75 (K110207), and Aloka SSD-5000

(K012080) for expanded indications.

4. Device Description: The Prosound Alpha 7 Ver. 6.0 Diagnostic Ultrasound System is a full feature imaging and analysis system. It consist of a mobile console that provides acquisition, processing and display capability. The user interface includes a computer type keyboard, specialized controls and a

5. Indications for Use: The device is intended for use by a qualified physician for ultrasound evaluation of Fetal, Abdominal, Intra-operative, Intra-operative (Neuro), Laparoscopic, Pediatric, Neonatal Cephalic, Trans-rectal & vaginal, Musculo-skeletal, Gynecological, Cardiac-(Adult, Neonatal, Pediatric), TEE & Peripheral Vascular.

The device is not indicated for Ophthalmic applications.

6.Comparison w/ Predicate Device:

The Prosound Alpha 7 Ver. 6.0 is technically comparable and substantially equivalent to the current Aloka SSD- Alpha 7 -(K072285). It has the same technological characteristics. key safety and effectiveness features, and has the same uses and basic operating modes as the predicate device.

Section b):

1. Non-clinical Tests: The device and its transducers have been evaluated for acoustic output, biocompatibility, cleaning & disinfection effectiveness, electromagnetic compatibility, as well as electrical and mechanical safety, and have been found to conform with applicable medical device safety standards.

2. Clinical Tests:

None Required.

Conclusion:

Intended uses and other key features are consistent with traditional clinical practices, FDA guidelines and established methods of patient examination. The design, development and quality process of the manufacturer conforms to 21 CFR 820, ISO 9001:2000 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effectiveness performance. Therefore, it is the opinion of Hitachi Aloka Medical, Ltd. that the Prosound Alpha 7 Ver. 6.0 Diagnostic Ultrasound System and its transducers are equivalent with respect to safety and effectiveness to its predicate and other currently cleared Hitachi Aloka Medical systems.



Food and Drug Administration 10903 New Hampshire Avenue Document Control Center – WO66-G609 Silver Spring, MD 20993-002

#### April 12, 2013

Hitachi Aloka Medical, Ltd. (Hitachi Aloka Medical AMERICA) % Mr. Michael S. Ogunleye 510(k) Program Manager/Medical Lead Auditor TUV Rheinland of North America 12 Commerce Road NEWTOWN CT 06470

Re: K122537

Trade/Device Name: Prosound Alpha 7 Ver. 6.0 Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system -

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: January 4, 2013 Received: March 13, 2013

#### Dear Mr. Ogunleye:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with Prosound Alpha 7 Ver. 6.0 Diagnostic Ultrasound System, as described in your premarket notification:

#### Transducer Model Number

UST-533	UST-534
UST-536	UST-547
UST-567	UST-675
UST677P (L&T)	UST-678 (C&L)
UST-984-5	ASU-1010

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ASU-1012	ASU-1013
UST-2265-2	UST-2266-5
UST-5045P-3.5	UST-5293-5
UST-5296	UST-5411
UST-5412	UST-5534T-7.5
UST-5536-7.5	UST-5543
UST-5548	UST-5550
UST-5712	UST-5713T
UST-9101-7.5	UST-9104-5
UST-9115-5	UST-9118
UST-9120	UST-9128
UST-9130	UST-9132 I/T
UST-9133	UST-9135P
UST-9136U	UST-9146 I/T
UST-52101	UST-52105
UST-52108	UST-52109
UST-52110S	UST-52114P
UST-52119S	UST-52120S
UST-52121S	UST-52124

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <a href="http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm">http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm</a> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21

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CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure(s)

# Indications for Use

510(k) Number (if known):	K122537
Device Name:	Prosound Alpha 7 Ver. 6.0 Diagnostic Ultrasound System
Indications for Use:	
Abdominal, Intra-operativ	r use by a qualified physician for ultrasound evaluation of Fetal ve (Neuro). Laparoscopic, Pediatric, Neonatal Cephalic, Trans- oskeletal, Gynecological, Cardiac (Adult, Neonatal, Pediatric). lar.
The device is not intended	d for ophthalmic applications.
•	
·	
Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR Over-The-Counter Use (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BE	LOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH,	Office of In Vitro Diagnostics and Radiological Health (OIR)
Offic	(Division Sign-Off) Division of Radiological Health ce of In Vitro Diagnostics and Radiological Health
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1.3.1

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical A - Linking	nu imag	d imaging or fluid flow analysis of the human body as follows:								
General	Clinical Application	<del> </del>	1 2			ode of Opera					
(Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)			
Ophthalmic	Ophthalmic	$\top$					<del>                                     </del>	<del></del>			
-	Fetal	P	P	P.	<del> </del>	P	Note 1	Note 2			
	Abdominal	P	P	P		P	Note I	Note 2			
	Intra-operative (Specify)	P	P	P		P	Note 1				
	Intra-operative (Neuro), Burr Hole	N	N	N	<del>-</del> 1	N	Note 1				
	Inter-operative, Laparoscopic	N	N	N		N	Note 1				
	Pediatric	N	N	N		N	Note 1				
Fetal Imaging	Small Organ (Specify)	P	P	P		P	Note I	Note 2			
& Other	Neonatal Cephalic	P	P	P		P	Note 1	Note 2			
	Adult Cephalic										
	Trans-rectal	P	P	Р		P	Note I				
·	Trans-vaginal	P	P	P		Р	Note I				
	Trans-urethral										
	Trans-esoph. (non-Card.)					•					
	Musculo-skeletal (Convent.)	P	P	Р		P	Note I	Note 2			
j	Musculo-skeletal (Superfical)				.						
	Other: Gynecological	P	P	P		P	Note 1	Note 2			
Į.	Cardiac Adult	P	P	P		P	Note 1	Note 2			
Cardiac	Cardiac Adult, TEE	N	N	N		N	Note I	Note 2			
Cardiac	Cardiac Pediatric, TEE	N	N	N		N	Note I	Note 2			
1	Cardiac Neonatal, TEE	N	N	N		N	Note 1	Note 2			
1	Cardiac, Pediatric	N	N	N		N	Note 1	Note 2			
1	Cardiac, Neonatal	N	N	N		N	Note I	Note 2			
<u> </u>	Intra-cardiac										
	Other (Specify)							<del>-</del>			
37 1	Peripheral vascular	P	P	P		P	Note I	Note 2			
	Other (Specify)						<del> </del>				

N = new indication for system; P= Previously cleared K072285, E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

Applications:- Intra-operative- (liver, pancreas, gall bladder, ....), Small Organ- (breast, testes, thyroid....).

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

System: <u>Prosound Alpha 7 Ver. 6.0</u> Transducer: UST-533

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application		Mode of Operation								
General (Track I Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)			
Ophthalmic	Ophthalmic										
	Fetal					<del></del>					
ì	Abdominal										
ĺ	Intra-operative (Specify)	Е	E	E		E	Note I	·			
	Intra-operative (Neuro), Burr Hole										
	Inter-operative, Laparoscopic										
	Pediatric							·			
Fetal Imaging	Small Organ (Specify)	1									
& Other	Neonatal Cephalic										
	Adult Cephalic							•			
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skeletal (Convent.)		1								
	Musculo-skeletal (Superfical)					·					
	Other: Gynecological										
	Cardiac Adult										
Co-di	Cardiac Adult, TEE							· · · · · · · · · · · · · · · · · · ·			
Cardiac	Cardiac Pediatric, TEE										
Į.	Cardiac Neonatal, TEE										
	Cardiac, Pediatric										
	Cardiac, Neonatal										
[	Intra-cardiac										
	Other (Specify)										
Peripheral	Peripheral vascular						<del></del>				
Vessel	Other (Specify)							·			

N = new indication for system; E = added to Alpha 7 under Appendix E,

Combined: Note I: B/M, B/PWD, M/CD, B/CD/PWD

Applications:- intra-operative- (liver, pancreas, gall bladder, ....),

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

System: Prosound Alpha 7 Ver. 6.0

Transducer: UST-534

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)			
Ophthalmic	Ophthalmic										
	Fetal										
	Abdominal			/			T				
	Intra-operative (Specify)	E	Е	Ē		Е	Note I				
	Intra-operative (Neuro), Burr Hole										
	Inter-operative, Laparoscopic										
	Pediatric										
Fetal Imaging	Small Organ (Specify)										
& Other	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal							•			
	Trans-urethral						-				
	Trans-esoph. (non-Card.)										
	Musculo-skeletal (Convent.)										
	Musculo-skeletal (Superfical)							•			
	Other: Gynecological										
-	Cardiac Adult					T.					
<u> </u>	Cardiac Adult, TEE										
Cardiac	Cardiac Pediatric, TEE										
	Cardiac Neonatal, TEE							·			
	Cardiac, Pediatric										
1	Cardiac, Neonatal						ļ <u> </u>				
1	Intra-cardiac										
	Other (Specify)										
Peripheral	Peripheral vascular										
Vessel	Other (Specify)										

N = new indication for system; E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Applications:- Intra-operative- (liver, pancreas, gall bladder, ....)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

System: Prosound Alpha 7 Ver. 6.0

Transducer: UST-536

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	T - '	Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)		
Ophthalmic	Ophthalmic	1 -								
	Fetal									
	Abdominal									
	Intra-operative (Specify)	Е	Е	E		E	Note I	,		
	Intra-operative (Neuro), Burr Hole									
	Inter-operative, Laparoscopic									
	Pediatric									
Fetal Imaging	Small Organ (Specify)	E	Е	Е		E	Note I			
& Other	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal							-		
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)			Ţ Ţ			<u> </u>			
	Musculo-skeletal (Convent.)									
	Musculo-skeletal (Superfical)									
	Other : Gynecological				-					
	Cardiac Adult									
	Cardiac Adult, TEE									
Cardiac	Cardiac Pediatric, TEE	T								
	Cardiac Neonatal, TEE									
	Cardiac, Pediatric									
Į	Cardiac, Neonatal									
	Intra-cardiac									
	Other (Specify)		•					·		
Peripheral	Peripheral vascular	Ε	Е	Е	-	E	Note 1			
Vessel	Other (Specify)						<del></del>			

N = new indication for system; E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

Applications:- Intra-operative- (liver, pancreas, gall bladder, ....), Small Organ- (breast, testes, thyroid....).

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

System: Prosound Alpha 7 Ver. 6.0

Transducer: UST-547

Intended Use: Diagnostic ultrasound i	imaging or fluid flow analysis of the human body as follo	we.

	Clinical Application	d imaging or fluid flow analysis of the human body as follows:  Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)		
Ophthalmic	Ophthalmic									
	Fetal	1					<del>                                     </del>			
ļ	Abdominal									
	Intra-operative (Specify)	Е	E	Ē		Е	Note I			
	Intra-operative (Neuro), Burr Hole	T								
1	Inter-operative, Laparoscopic	]								
ĺ	Pediatric									
Fetal Imaging	Small Organ (Specify)	Е	E	Е		E	Note 1			
& Other	Neonatal Cephalic	E	Е	Е		E	Note 1			
	Adult Cephalic				]-					
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Convent.)									
	Musculo-skeletal (Superfical)									
	Other: Gynecological ,									
i	Cardiac Adult		1	ĺ						
a 1:	Cardiac Adult, TEE									
Cardiac	Cardiac Pediatric, TEE									
	Cardiac Neonatal, TEE									
1	Cardiac, Pediatric		, -							
	Cardiac, Neonatal									
į.	Intra-cardiac							,		
	Other (Specify)									
Peripheral	Peripheral vascular									
	Other (Specify)			· ·						

N = new indication for system; E = added to Alpha 7 under Appendix E,

Combined: Note I: B/M, B/PWD, M/CD, B/CD/PWD

Applications:- Intra-operative- (liver, pancreas, gall bladder, ....), Small Organ- (breast, testes, thyroid....).

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

System: Prosound Alpha 7 Ver. 6.0

Transducer: UST-567

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

<u> </u>	Clinical Application	T				ode of Opera		
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal							
	Intra-operative (Specify)	,						
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							•
Fetal Imaging	Small Organ (Specify)	E	E	E		Е	Note 1	
& Other	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	<u> </u>						
	Trans-vaginal		<u> </u>		}			
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)	E	E	E		E	Note I	
	Musculo-skeletal (Superfical)							
	Other: Gynecological							
	Cardiac Adult							
`a	Cardiac Adult, TEE							
Cardiac	Cardiac Pediatric, TEE		[					
<u> </u>	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
L	Cardiac, Neonatal							
Ĺ	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vascular	E	Ė	Е		Е	Note 1	
Vessel	Other (Specify)							· ·

N = new indication for system; E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Applications:- Small Organ- (breast, testes, thyroid....).

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

System: Prosound Alpha 7 Ver. 6.0

Transducer: UST-675

	Clinical Application	nd imaging or fluid flow analysis of the human body as follows:  Mode of Operation								
General (Track I Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)		
Ophthalmic	Ophthalmic	1		<del>                                     </del>	<u> </u>		<del> </del>			
	Fetal	<del>                                     </del>	<del>                                     </del>	<del> </del>	-		<del> </del>			
	Abdominal	T	<u> </u>		<del></del>					
	Intra-operative (Specify)	† · · · · ·					<del> </del>			
	Intra-operative (Neuro), Burr Hole									
	Inter-operative, Laparoscopic	1		-			<del></del>			
Fetal Imaging	Pediatric						<del></del> -			
	Small Organ (Specify)						···			
& Other	Neonatal Cephalic									
	Adult Cephalic						- <del></del>			
	Trans-rectal	P	Р	Р		P	Note I			
ĺ	Trans-vaginal	Р	Р	P	<del></del>	P	Note 1			
	Trans-urethral						11010 1			
	Trans-esoph. (non-Card.)						<del></del>			
	Musculo-skeletal (Convent.)	1								
	Musculo-skeletal (Superfical)									
	Other: Gynecological							<del></del> .		
	Cardiac Adult									
	Cardiac Adult, TEE									
Cardiac	Cardiac Pediatric, TEE									
į	Cardiac Neonatal, TEE						<del></del>	<del></del>		
	Cardiac, Pediatric							<del></del>		
Ţ	Cardiac, Neonatal									
<u>l</u>	Intra-cardiac				<del></del>		<del></del>	····		
	Other (Specify)									
	Peripheral vascular		<u> </u>			· <del></del>				
Vessel	Other (Specify)									

N = new indication for system; P= Previously cleared K072285

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

System: Prosound Alpha 7 Ver. 6.0 Transducer: UST677P (L&T)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)	
Ophthalmic	Ophthalmic	1		i			· · ·		
	Fetal	1							
	Abdominal				· · · · · · · · · · · · · · · · · · ·				
	Intra-operative (Specify)								
	Intra-operative (Neuro), Burr Hole	İ							
	Inter-operative, Laparoscopic								
ł	Pediatric								
Fetal Imaging	Small Organ (Specify)								
& Other	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	E	Е	E		E	Note 1		
	Trans-vaginal							,	
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Convent.)								
	Musculo-skeletal (Superfical)								
	Other: Gynecological								
į	Cardiac Adult								
Cardiac	Cardiac Adult, TEE								
Cardiac	Cardiac Pediatric, TEE								
ļ	Cardiac Neonatal, TEE								
	Cardiac, Pediatric								
1	Cardiac, Neonatal								
ļ	Intra-cardiac	$\perp$							
	Other (Specify)			j			·		
Peripheral	Peripheral vascular								
Vessel	Other (Specify)								

N = new indication for system; E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Applications:- Intra-operative-(liver, pancreas, gall bladder, ....)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

System: Prosound Alpha 7 Ver. 6.0 Transducer: UST-678 (C&L)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	i innagi	g v: 11	4.0 11017		ode of Operat		
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic	Ť –	<b>–</b>					
	Fetal							
	· Abdominal							-
1	Intra-operative (Specify)	1 .						
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
Fetal Imaging	Small Organ (Specify)							
& Other	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	Е	Е	E		Е	Note I	·
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other: Gynecological							
	Cardiac Adult					ļ		
G 1:	Cardiac Adult, TEE							
Cardiac	Cardiac Pediatric, TEE							
İ	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
ļ	Cardiac, Neonatal							
Ţ	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vascular							
Vessel	Other (Specify)							

N = new indication for system; E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Applications:- Intra-operative- (liver, pancreas, gall bladder, ....)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

System: <u>Prosound Alpha 7 Ver. 6.0</u> Transducer: UST-984-5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:	wer
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	Clinical Application	d imaging or fluid flow analysis of the human body as follows:  Mode of Operation									
General	Specific	В	М	PWD	<del>,</del>	<del></del>					
(Track 1	(Tracks 1 & 3)	<sup>b</sup>	IVI	PWD	CWD	Color Doppler	Combined	Other			
Only)	(1.10.0.2.2.2)	Ì	ļ		]	Dobbier	(Specify)	(Specify)			
Ophthalmic	Ophthalmic										
	Fetal	Е	Е	Е		E	Note 1				
	Abdominal										
	Intra-operative (Specify)										
	Intra-operative (Neuro), Burr Hole	1									
}	Inter-operative, Laparoscopic										
N.	Pediatric										
Fetal Imaging	Small Organ (Specify)										
& Other	Neonatal Cephalic		1								
	Adult Cephalic										
•	Trans-rectal										
	Trans-vaginal	E	E	Е		Е	Note !				
	Trans-urethral						·				
	Trans-esoph. (non-Card.)										
·	Musculo-skeletal (Convent.)		_								
	Musculo-skeletal (Superfical)							<del></del>			
	Other: Gynecological	Е	E	E		E	Note I				
	Cardiac Adult		_								
	Cardiac Adult, TEE										
Cardiac	Cardiac Pediatric, TEE				•						
	Cardiac Neonatal, TEE	İ									
. [	Cardiac, Pediatric										
	Cardiac, Neonatal						_				
Ĺ	Intra-cardiac					-					
	Other (Specify)										
Peripheral	Peripheral vascular										
	Other (Specify)										

N = new indication for system; E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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System: Prosound Alpha 7 Ver. 6.0

Transducer: ASU-1010

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	1		<u> </u>		ode of Operat		
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic		İ	-				
	Fetal	Р	P	P		P	Note 1	
]	Abdominal	P	P	P		P	Note i	
	Intra-operative (Specify)							<del> </del>
	Intra-operative (Neuro), Burr Hole							
ļ	Inter-operative, Laparoscopic							
	Pediatric			•		7		
Fetal Imaging	Small Organ (Specify)							
& Other	Neonatal Cephalic						·	
	Adult Cephalic					_		
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							<u> </u>
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							· · · · · · · · · · · · · · · · · · ·
	Other: Gynecological	P	P	P		P	Note 1	
	Cardiac Adult							
Cardiac	Cardiac Adult, TEE							
Cardiac	Cardiac Pediatric, TEE							
ļ	Cardiac Neonatal, TEE		_					
1	Cardiac, Pediatric							
L	Cardiac, Neonatal							
Į.	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vascular							
Vessel	Other (Specify)							

N = new indication for system; P= Previously cleared K072285,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

System: Prosound Alpha 7 Ver. 6.0

Transducer: ASU-1012

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	nd imaging or fluid flow analysis of the human body as follows:  Mode of Operation								
General (Track I Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)		
Ophthalmic	Ophthalmic	<del> </del>	<del> </del>		-	<del>- · · ·</del>	<del>                                     </del>			
	Fetal	E	Ė	E		E	Note I			
	Abdominal	1				<del></del>				
	Intra-operative (Specify)	7	-							
	Intra-operative (Neuro), Burr Hole	1		-						
	Inter-operative, Laparoscopic						· · · · · ·			
	Pediatric									
Fetal Imaging	Small Organ (Specify)									
& Other	Neonatal Cephalic							<del></del>		
•	Adult Cephalic									
	Trans-rectal						-			
	Trans-vaginal	E	E	E		E	Note I			
	Trans-urethral									
	Trans-esoph. (пол-Card.)						· -			
	Musculo-skeletal (Convent.)							V		
	Musculo-skeletal (Superfical)							· · · · · · · · · · · · · · · · · · ·		
	Other: Gynecological	E	E	E		E	Note 1			
	Cardiac Adult									
[	Cardiac Adult, TEE									
Cardiac	Cardiac Pediatric, TEE									
. ]	Cardiac Neonatal, TEE									
ĺ.	Cardiac, Pediatric							<del></del> -		
	Cardiac, Neonatal									
[	Intra-cardiac									
	Other (Specify)									
	Peripheral vascular				<del></del>   -					
Vessel	Other (Specify)									

N = new indication for system; E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

System: <u>Prosound Alpha 7 Ver. 6.0</u> Transducer: ASU-1013

····	Intended Use: Diagnostic ultrasou Clinical Application				M	ode of Opera	tion	
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic			<del></del>			<del>                                     </del>	
	Fetal	1-	1				<del>                                     </del>	
•	Abdominal		T-	<b> </b> -	<u> </u>		<del>                                     </del>	<del></del>
	Intra-operative (Specify)			T			<del>                                     </del>	
	Intra-operative (Neuro), Burr Hole		$T^-$					
	Inter-operative, Laparoscopic			,				
	Pediatric							
Fetal Imaging	Small Organ (Specify)	E_	E	Е		E	Note I	<del></del>
& Other	Neonatal Cephalic							
	Adult Cephalic							· · · · ·
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral	L						
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)	Е	E	Е		E	Note !	
	Musculo-skeletal (Superfical)							-
	Other: Gynecological							
Į.	Cardiac Adult							
Cardiac	Cardiac Adult, TEE							
Cardiac	Cardiac Pediatric, TEE							
1	Cardiac Neonatal, TEE							
[	Cardiac, Pediatric							
[	Cardiac, Neonatal							
Ļ	Intra-cardiac	$\Box$						
	Other (Specify)							
<u> </u>	Peripheral vascular	E	Е	Е		E	Note I	
Vessel	Other (Specify)					·		

N = new indication for system; E = added to Alpha 7 under Appendix E

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Applications:- Small Organ- (breast, testes, thyroid....).

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

System: Prosound Alpha 7 Ver. 6.0

Transducer: UST-2265-2

	Intended Use: Diagnostic ultrasoun	d imagi	ng or fl	uid flow :				<u></u>
	Clinical Application	<del> </del>				ode of Operat		
General (Track f Only)	Specific (Tracks I & 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal					-		
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric						<u> </u>	
Fetal Imaging & Other	Small Organ (Specify)							
	Neonatal Cephalic		_					-
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral					Ţ		
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other: Gynecological							
	Cardiac Adult				E			
[	Cardiac Adult, TEE							
Cardiac	Cardiac Pediatric, TEE							
ĺ	Cardiac Neonatal, TEE							
. [	Cardiac, Pediatric							
[	Cardiac, Neonatal							
Ţ	Intra-cardiac							.,,

Other (Specify) N = new indication for system; E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

Other (Specify)

Peripheral vascular

Peripheral

Vessel

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

System: <u>Prosound Alpha 7 Ver. 6.0</u> Transducer: UST-2266-5

Intended Use: Diagnostic ultrasound	imaging or fluid flow anal	vsis of the buman hody as follows:
intended Ode. Diagnostic diti asound	maging of nato flow and	vsis of the Rubball body as lonows:

	Clinical Application	Mode of Operation								
General	Specific	В	M	PWD	CWD	Color	Combined	Other		
(Track 1	(Tracks I & 3)	J		ļ	i I	Doppler	(Specify)	(Specify)		
Only)		<u> </u>								
Ophthalmic	Ophthalmic	<u> </u>								
1	Fetal	ļ								
1	Abdominal									
}	Intra-operative (Specify)									
ļ	Intra-operative (Neuro), Burr Hole									
ļ	Inter-operative, Laparoscopic									
]	Pediatric									
Fetal Imaging	Small Organ (Specify)									
& Other	Neonatal Cephalic		_		<u>.</u>					
	Adult Cephalic									
į	Trans-rectal									
1	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Convent.)									
j	Musculo-skeletal (Superfical)		1							
	Other: Gynecological									
į.	Cardiac Adult				E					
	Cardiac Adult, TEE		[							
Cardiac	Cardiac Pediatric, TEE									
1	Cardiac Neonatal, TEE						_			
L	Cardiac, Pediatric									
Ĺ	Cardiac, Neonatal							-		
	Intra-cardiac									
	Other (Specify)						-			
	Peripheral vascular				E					
Vessel	Other (Specify)									

N = new indication for system; E = added to Alpha 7 under Appendix E,

Combined: Note I: B/M, B/PWD, M/CD, B/CD/PWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

System: <u>Prosound Alpha 7 Ver. 6.0</u> Transducer: UST-5045P-3.5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	l III.g	ing of 1	dia 11011		ode of Operat		
General (Track 1 Only)	Specific (Tracks I & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic	<b>†</b>						
	Fetal	1			İ	<del></del>		
	Abdominal	E	E	Е		E	Note I	
1	Intra-operative (Specify)			-				****
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
Fetal Imaging	Small Organ (Specify)							
& Other	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
i	Trans-vaginal							- · · · · ·
	Trans-urethral							
	Trans-esoph. (non-Card.)		_					
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)				_			
	Other: Gynecological	E	Е	E		Е	Note i	
!	Cardiac Adult							
Cardiac	Cardiac Adult, TEE							
Cardiac	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
1	Cardiac, Pediatric							
1	Cardiac, Neonatal	·						
[_	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vascular							
Vessel	Other (Specify)							

N = new indication for system; E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

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System: Prosound Alpha 7 Ver. 6.0

Transducer: UST-5293-5

	Intended Use: Diagnostic ultrasound	l imagi:	ng or fl	uid flow a	inalysis of	the human be	dy as follows:	
	Clinical Application					ode of Operat		
General	Specific	В	M	PWD	CWD	Color	Combined	_
(Track 1	(Tracks 1 & 3)	Ī	ļ	Ē.		n	1 (0 .6 )	

Fetal Abdominal Intra-operative (Specify) Intra-operative (Neuro), Burr Hole Inter-operative, Laparoscopic Pediatric	obined Other ecify) (Specify)
Abdominal Intra-operative (Specify) Intra-operative (Neuro), Burr Hole Inter-operative, Laparoscopic Pediatric	<del></del>
Intra-operative (Specify) Intra-operative (Neuro), Burr Hole Inter-operative, Laparoscopic Pediatric	
Intra-operative (Neuro), Burr Hole Inter-operative, Laparoscopic Pediatric	
Inter-operative, Laparoscopic Pediatric	
Pediatric	
<del></del>	
Fetal Imagina Crast Organ (Cassifa)	
& Other Neonatal Cephalic	
Adult Cephalic	
Trans-rectal Trans-rectal	
Trans-vaginal Trans-vaginal	
Trans-urethral	
Trans-esoph. (non-Card.)	
Musculo-skeletal (Convent.)	
Musculo-skeletal (Superfical)	
Other: Gynecological	
Cardiac Adult	
Cardiac Adult, TEE N N N N Note	l Note 2
Cardiac Pediatric, TEE	
Cardiac Neonatal, TEE	
Cardiac, Pediatric	
Cardiac, Neonatal	
Intra-cardiac	
Other (Specify)	
Peripheral Peripheral vascular	
Vessel Other (Specify)	

N = new indication for system; P= Previously cleared-K032875

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD, Note 2: B/CWD, B/CD/CWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

System: Prosound Alpha 7 Ver. 6.0

Transducer: UST-5296

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows: Clinical Application Mode of Operation General Specific М **PWD** CWD Color Combined Other (Track 1 (Tracks 1 & 3) Doppler (Specify) (Specify) (yinO Ophthalmic Ophthalmic Fetal Abdominal Intra-operative (Specify) Intra-operative (Neuro), Burr Hole Inter-operative, Laparoscopic Pediatric Fetal Imaging Small Organ (Specify) & Other Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Musculo-skeletal (Convent.) Musculo-skeletal (Superfical) Other: Gynecological Cardiac Adult Cardiac Adult, TEE Cardiac Cardiac Pediatric, TEE Cardiac Neonatal, TEE Cardiac, Pediatric Cardiac, Neonatal N N Note I Note 2 Intra-cardiac

N = new indication for system; P= Previously cleared K072285,

Other (Specify)

Other (Specify)

Peripheral vascular

Peripheral

Vessel

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD, Note 2: B/CWD, B/CD/CWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

System: <u>Prosound Alpha 7 Ver. 6.0</u> Transducer: UST-5411

intended Ose: Diagnostic ditrasounc	i imaging or fluid flow analysis of the human body as follows:
Clinical Application	M-3 CO 11

<u> </u>	Clinical Application	I	7			ode of Opera		
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic	<del>                                     </del>	1	<del>                                     </del>			<del> </del>	
	Fetal	1		<del>                                     </del>			-	
•	Abdominal	<b>†</b>	1	<del>                                     </del>	<b>├</b> ~~		<del> </del>	
	Intra-operative (Specify)	1	<del> </del>				<del> </del>	<del></del> _
	Intra-operative (Neuro), Burr Hole						<del> </del>	
	Inter-operative, Laparoscopic		1	T				
	Pediatric		1		-			· <del>-</del> · · · ·
Fetal Imaging	Small Organ (Specify)	Е	E	Е		Е	Note I	<del></del>
& Other	Neonatal Cephalic			-	<u> </u>	<del></del>		
	Adult Cephalic			1				
	Trans-rectal		-					<del> </del>
	Trans-vaginal						-	<del></del>
	Trans-urethral							
	Trans-esoph. (non-Card.)					- 1		
	Musculo-skeletal (Convent.)	E	E	Е		E	Note 1	
	Musculo-skeletal (Superfical)							
	Other: Gynecological						<del></del>	
	Cardiac Adult							
a	Cardiac Adult, TEE							
Cardiac	Cardiac Pediatric, TEE				·			
1	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
Ĺ	Cardiac, Neonatal					<del></del>		
[	Intra-cardiac		1					
	Other (Specify)							
Peripheral	Peripheral vascular	E	E	Е		E	Note I	
Vessei	Other (Specify)							

E = added to Alpha 7 under Appendix E,

Combined: Note I: B/M, B/PWD, M/CD, B/CD/PWD Applications:- Small Organ- (breast, testes, thyroid....).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

System: Prosound Alpha 7 Ver. 6.0

Transducer: UST-5412

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	1	, in <u>6</u> 0 i	Huid HO		lode of Opera		·····
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWI		Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic	<del> </del>	<del>                                     </del>	<del>                                     </del>	<del></del>		<del></del>	
	Fetal	1	<del>                                     </del>	<del>                                     </del>	<del></del>		<del> </del>	
	Abdominal	<u> </u>		<u> </u>			1	
	Intra-operative (Specify)			<del>                                     </del>			<del> -</del>	<del></del> -
	Intra-operative (Neuro), Burr Hole				_			
	Inter-operative, Laparoscopic			1			<del></del>	
	Pediatric			1			<del></del>	
Fetal Imaging	Small Organ (Specify)	Р	P	P		P	Note !	Note 2
& Other	Neonatal Cephalic			ļ				Note 2
	Adult Cephalic			1				·
	Trans-rectal							<del></del>
	Trans-vaginal							
	Trans-urethral				1-1	<del></del> -		
_	Trans-esoph. (non-Card.)							
-	Musculo-skeletal (Convent.)	P	P	Р		P	Note 1	Note 2
	Musculo-skeletal (Superfical)		_					
<u> </u>	Other: Gynecological					-		
	Cardiac Adult							
C1:	Cardiac Adult, TEE			<del></del>				
Cardiac	Cardiac Pediatric, TEE				T		<del>-  -</del>	-
<u> </u>	Cardiac Neonatal, TEE							·
L	Cardiac, Pediatric			···				
L	Cardiac, Neonatal							
. F-	Intra-cardiae							<del>-</del>
	Other (Specify)							<del></del>
	Peripheral vascular	P	P	P		Р	Note I	Note 2
Vessel = Previously elea	Other (Specify)			j		<del></del>		.,010 2

P= Previously cleared K072285,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Applications:- Small Organ- (breast, testes, thyroid....).

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

System: Prosound Alpha 7 Ver. 6.0 Transducer: UST-5534T-7.5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	nd imaging or fluid flow analysis of the human body as follows:  Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)		
Ophthalmic	Ophthalmic	1	1	<del> </del>	† ' '		1			
	Fetal	1	<del>                                     </del>	1			<del>                                     </del>			
	Abdominal	1		ļ			<del> </del>			
	Intra-operative (Specify)	E	Е	E		E	Note I			
	Intra-operative (Neuro), Burr Hole							· · · · · · · · · · · · · · · · · · ·		
	Inter-operative, Laparoscopic									
	Pediatric		-							
Fetal Imaging	Small Organ (Specify)	Е	Е	Е		Е	Note !	<del></del>		
& Other	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral		]							
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Convent.)									
	Musculo-skeletal (Superfical)									
	Other: Gynecological				.					
į	Cardiac Adult		}							
· · ·	Cardiac Adult, TEE									
Cardiac	Cardiac Pediatric, TEE									
	Cardiac Neonatal, TEE									
	Cardiac, Pediatric									
L	Cardiac, Neonatal									
Į	Intra-cardiac	7								
	Other (Specify)									
Peripheral	Peripheral vascular	Е	E	Е		Е	Note 1			
Vessel	Other (Specify)									

E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

Applications:- Intra-operative- (liver, pancreas, gall bladder, ....), Small Organ- (breast, testes, thyroid....).

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

System: Prosound Alpha 7 Ver. 6.0

Transducer: UST-5536-7.5

Intended Use: Diagnosti	c ultrasound	imaging or flui	d flow analysis of	the human body as follows:

<u></u>	Clinical Application	1	115, 01 11	uio 110 11 .		ode of Operat		
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							· · · · · · · · · · · · · · · · · · ·
	Fetal						1	
1	Abdominal	1						-
1	Intra-operative (Specify)							
İ	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic	N	N	N		N	Note 1	
	Pediatric					<del></del> -		
Fetal Imaging	Small Organ (Specify)							
& Other	Neonatal Cephalic		•					
1	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal		[					
	Trans-urethral							
İ	Trans-esoph. (non-Card.)							
	Musculo-skeletał (Convent.)				l,			
	Musculo-skeletal (Superfical)							
	Other: Gynecological							
	Cardiac Adult						-	
	Cardiac Adult, TEE							
Cardiac	Cardiac Pediatric, TEE							7
l	Cardiac Neonatal, TEE	,						
	Cardiac, Pediatric		_			ľ		
	Cardiac, Neonatal		_					
Į	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vascular							
Vessel	Other (Specify)							

N = new indication for system; P= Previously cleared-K 032875

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

Application: Intra-operative: (liver, pancreas, gall bladder,....)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

System: Prosound Alpha 7 Ver. 6.0

Transducer: UST-5543

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	1				ode of Operat		
General (Track I Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic	1	$\top$			-		
	Fetal	1	1					
	Abdominal							
ł	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic					•		
	Pediatric							-
Fetal Imaging	Small Organ (Specify)	E	E	Е		E	Note i	
& Other	Neonatal Cephalic							
	Adult Cephalic							
•	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)	E	E	E		E	Note I	
	Musculo-skeletal (Superfical)							<u> </u>
	Other: Gynecological							
	Cardiac Adult							
Cardiac	Cardiac Adult, TEE							
Cardiac	Cardiac Pediatric, TEE							
]	Cardiac Neonatal, TEE							
ļ	Cardiac, Pediatric							
į.	Cardiac, Neonatal							
Ĺ	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vascular	E	E	E		E	Note I	
Vessel	Other (Specify)						ļ	

E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Applications:- Small Organ- (breast, testes, thyroid....).

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

#### 510(K)

#### DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0

Transducer: UST-5548

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Intended Use: Diagnostic ultrasoun Clinical Application	T	6 0. 1	ara kis k		ode of Operat		
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic	1						
	Fetal							
	Abdominal		1					
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic		<u></u>				<u> </u>	
	Pediatric	L						
Fetal Imaging	Small Organ (Specify)	E	E	E		E	Note 1	
& Other	Neonatal Cephalic							
	Adult Cephalic		İ				-	
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							· <u>·</u> ···
	Musculo-skeletal (Convent.)	,						
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
	Cardiac Adult							
]	Cardiac Adult, TEE							
Cardiac	Cardiac Pediatric, TEE							
Į	Cardiac Neonatal, TEE	[						
<u> </u>	Cardiac, Pediatric		<u>.  </u>					
į	Cardiac, Neonatal							
<u>[</u>	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vascular	Е	Е	E		Е	Note I	
Vessel	Other (Specify)						<u> </u>	

E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Applications:- Small Organ- (breast, testes, thyroid....).

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

System: <u>Prosound Alpha 7 Ver. 6.0</u> Transducer: UST-5550

W / N N W N	
Intended Use: Diagnostic ultrasom	d imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Ī				ode of Operat		
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic	<u> </u>						
	Fetal							
	Abdominal			-				<del></del>
i	Intra-operative (Specify)	·						
İ	Intra-operative (Neuro), Burr Hole							
ł	Inter-operative, Laparoscopic	N	N	N		N	Note I	
	Pediatric							
Fetal Imaging	Small Organ (Specify)							
& Other	Neonatal Cephalic							
	Adult Cephalic	Ī		_				•
	Trans-rectal	l						
	Trans-vaginal		i l'					
	Trans-urethral							
	Trans-esoph. (пол-Card.)							
	Musculo-skeletal (Convent.)	i						
ļ	Musculo-skeletal (Superfical)							
	Other: Gynecological							
L	Cardiac Adult							
	Cardiac Adult, TEE							
Cardiac	Cardiac Pediatric, TEE					• [		
	Cardiac Neonatal, TEE		_					
.į.	Cardiac, Pediatric		j					
L	Cardiac, Neonatal							
Į	Intra-cardiac							
	Other (Specify)							
	Peripheral vascular							
Vessel	Other (Specify)			,				

N = new indication for system;

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Applications:- Small Organ- (breast, testes, thyroid....).

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

System: Prosound Alpha 7 Ver. 6.0

Transducer; UST-5712

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Intended Use: Diagnostic ultrasoun Clinical Application	Timag.	ing vi ti	1414 2147 2		ode of Operat		
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
	Fetal Abdominal Intra-operative (Specify) Intra-operative (Neuro), Burr Hole Inter-operative, Laparoscopic							
	Pediatric	<u> </u>						
Fetal Imaging & Other	Small Organ (Specify) Neonatal Cephalic	Е	E	Е		E	Note 1	
	Adult Cephalic							
•	Trans-rectal							
	Trans-vaginal Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)	E	E	Е		Е	Note I	
	Musculo-skeletal (Superfical)							
	Other: Gynecological							
	Cardiac Adult							
	Cardiac Adult, TEE							
Cardiac	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE	.						
	Cardiac, Pediatric							
[	Cardiac, Neonatal							
[	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vascular	Е	Е	Е		Е	Note I	
Vessel	Other (Specify)			]	İ		ĺ	_

E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Applications:- Small Organ- (breast, testes, thyroid....).

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

System: Prosound Alpha 7 Ver. 6.0

Transducer: UST-5713T

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application					ode of Operat		
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal							
	Intra-operative (Specify)	E	E	E		E	Note 1	
	Intra-operative (Neuro), Burr Hole	Ι						
	Inter-operative, Laparoscopic							
<u> </u>	Pediatric							
Fetal Imaging	Small Organ (Specify)	E	E	Е		Ε.	Note I	
& Other	Neonatal Cephalic				-			
•	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other: Gynecological					1		ı
	Cardiac Adult							
	Cardiac Adult, TEE							
Cardiac	Cardiac Pediatric, TEE							
į	Cardiac Neonatal, TEE	i						
į.	Cardiac, Pediatric							
L	Cardiac, Neonatal	[						
Ĺ	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vascular	Е	E	E		E	Note I	
Vessel	Other (Specify)							

E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

Applications:- Intra-operative- (liver, pancreas, gall bladder, ....), Small Organ- (breast, testes, thyroid....).

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

System: <u>Prosound Alpha 7 Ver. 6.0</u> Transducer: UST-9101-7.5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)			
Ophthalmic	Ophthalmic		İ				<u> </u>				
	Fetal						<del>  </del>	· · · · · · · · · · · · · · · · · · ·			
-	Abdominal	P	P	Р		P	Note I				
	Intra-operative (Specify)						·				
	Intra-operative (Neuro), Burr Hole										
	Inter-operative, Laparoscopic	L									
	Pediatric	N	N	N		N	Note I				
Fetal Imaging	Small Organ (Specify)										
& Other	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal		_								
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skeletal (Convent.)										
i	Musculo-skeletal (Superfical)										
	Other: Gynecological										
	Cardiac Adult										
Cardiac	Cardiac Adult, TEE		.								
Cardiac	Cardiac Pediatric, TEE						•				
	Cardiac Neonatal, TEE										
	Cardiac, Pediatric										
	Cardiac, Neonatal										
ļ	Intra-cardiac										
	Other (Specify)										
Peripheral	Peripheral vascular										
Vessel	Other (Specify)				-						

N = new indication for system; P= Previously cleared K072285, E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

Applications:- Intra-operative- (liver, pancreas, gall bladder, ....), Small Organ- (breast, testes, thyroid....).

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

System: <u>Prosound Alpha 7 Ver. 6.0</u> Transducer: UST-9104-5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

,	Clinical Application	d imaging or fluid flow analysis of the human body as follows:  Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)		
Ophthalmic	Ophthalmic									
	Fetal									
	Abdominal			Ĺ						
	Intra-operative (Specify)	E	Е	Е		Е	Note 1			
	Intra-operative (Neuro), Burr Hole									
	Inter-operative, Laparoscopic									
	Pediatric									
Fetal Imaging	Small Organ (Specify)	E	E.	E		E	Note I			
& Other	Neonatal Cephalic	E	E	Ė		E	Note I			
	Adult Cephalic									
	Trans-rectal	,								
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Convent.)			·						
	Musculo-skeletal (Superfical)									
	Other: Gynecological									
Cardiac	Cardiac Adult					J				
	Cardiac Adult, TEE									
	Cardiac Pediatric, TEE							· <u></u>		
	Cardiac Neonatal, TEE									
	Cardiac, Pediatric									
	Cardiac, Neonatal									
	Intra-cardiac									
	Other (Specify)									
Peripheral	Peripheral vascular			[						
Vessel	Other (Specify)		- T							

E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Applications:- Intra-operative- (liver, pancreas, gall bladder, ....)

> (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)
> Prescription Use (Per 21 CFR 801.109)

System: Prosound Alpha 7 Ver. 6.0

Transducer: UST-9115-5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		d imaging or fluid flow analysis of the human body as follows:  Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)	
Ophthalmic	Ophthalmic	1						<del></del>	
	Fetal	1							
	Abdominal	E	E	Е		E	Note I		
	Intra-operative (Specify)								
	Intra-operative (Neuro), Burr Hole	I						<u> </u>	
ĺ	Inter-operative, Laparoscopic								
<u> </u>	Pediatric, Abdominal								
Fetal Imaging	Small Organ (Specify)								
& Other	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
•	Trans-urethral								
	Trans-esoph. (non-Card.)					Ī			
	Musculo-skeletal (Convent.)								
	Musculo-skeletal (Superfical)					· l			
	Other: Gynecological	E	Е	E		E	Note 1		
	Cardiac Adult								
C4:	Cardiac Adult, TEE								
Cardiac	Cardiac Pediatric, TEE								
	Cardiac Neonatal, TEE								
	Cardiac, Pediatric								
	Cardiac, Neonatal								
ļ	Intra-cardiac						<u> </u>		
	Other (Specify)								
Peripheral	Peripheral vascular	[_							
Vessel	Other (Specify)					/		- 1	

N = new indication for system;

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

System: Prosound Alpha 7 Ver. 6.0

Transducer: UST-9118

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Antended Ose: Diagnostic ultrasoun	nd imaging or fluid flow analysis of the human body as follows:									
Clinical Application			Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)			
Ophthalmic	Ophthalmic		_								
	Fetal	P	P	P		Р	Note I				
	Abdominal	1	ļ								
	Intra-operative (Specify)		, ,								
	Intra-operative (Neuro), Burr Hole	Ī									
	Inter-operative, Laparoscopic			•							
	Pediatric										
Fetal Imaging	Small Organ (Specify)										
& Other	Neonatal Cephalic						-				
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal	Р	P	Р		P	Note i				
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skeletal (Convent.)		Ţ								
	Musculo-skeletal (Superfical)										
	Other: Gynecological	P	P	P		P	Note I				
	Cardiac Adult										
	Cardiac Adult, TEE							-			
Cardiac	Cardiac Pediatric, TEE										
Į.	Cardiac Neonatal, TEE	_ [									
j	Cardiac, Pediatric					.		-			
	Cardiac, Neonatal	T									
	Intra-cardiac										
	Other (Specify)										
	Peripheral vascular										
Vessel	Other (Specify)										

P= Previously cleared K072285,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

Applications:- Intra-operative- (liver, pancreas, gall bladder, ....), Small Organ- (breast, testes, thyroid....).

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

System: Prosound Alpha 7 Ver. 6.0

Transducer: UST-9120

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application				<u> </u>	ode of Operat		
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
	Fetal						† · · · · · · †	
	Abdominal							-
	Intra-operative (Specify)	P	P	Р		P	Note I	
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric						1	
Fetal Imaging	Small Organ (Specify)		1					
& Other	Neonatal Cephalic	Р	P	P		P	Note I	· · ·
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal		f				ĺ	
j	Trans-urethral							
	Trans-esoph. (non-Card.)							• •
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							-
	Other: Gynecological							
į	Cardiac Adult							
0	Cardiac Adult, TEE							· · · · ·
Cardiac	Cardiac Pediatric, TEE							_
Ĺ	Cardiac Neonatal, TEE							
1	Cardiac, Pediatric							
·	Cardiac, Neonatal							
1	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vascular							
Vessel	Other (Specify)							

P= Previously cleared K072285,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Applications:- Intra-operative- (liver, pancreas, gall bladder, ....)

## (PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

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# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: <u>Prosound Alpha 7 Ver. 6.0</u> Transducer: UST-9128

	Intended Use: Diagnostic ultrasoun Clinical Application				Mo	de of Operat	ion	
General (Track I Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic						<del> </del>	<del></del>
	Fetal	1 -						<u>_</u> _
	Abdominal	Е	Е	E		E	Note 1	
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric, Abdominal							
Fetal Imaging	Small Organ (Specify)							<del></del>
& Other	Neonatal Cephalic		1					
	Adult Cephalic							•
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
j	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
į	Musculo-skeletal (Superfical)				<del></del>	· · · · · · · · · · · · · · · · · · ·		
	Other: Gynecological					-		
	Cardiac Adult							
[	Cardiac Adult, TEE							
Cardiac	Cardiac Pediatric, TEE							
[	Cardiac Neonatal, TEE							
Ĺ	Cardiac, Pediatric				-+			·
L	Cardiac, Neonatal					-		<del></del>
	Intra-cardiac							
	Other (Specify)						-	· ·
Peripheral	Peripheral vascular							
	Other (Specify)		-			<del></del>		

N = new indication for system;

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

System: <u>Prosound Alpha 7 Ver. 6.0</u> Transducer: UST-9130

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	1	<u>. 5 1</u>	alo nott		ode of Opera		
General (Track 1 · Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic	1					<del> </del> -	
	Fetal	P	Р	P		Р	Note 1	Note 2
	Abdominal	P	P	Р		P	Note !	Note 2
•	Intra-operative (Specify)	1						
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
Fetal Imaging	Small Organ (Specify)			1				
& Other	Neonatal Cephalic							<del></del>
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral				7			
	Trans-esoph. (non-Card.)			"				
	Musculo-skeletal (Convent.)				-			1
	Musculo-skeletal (Superfical)				_			
	Other: Gynecological	Р	Р	P		Р	Note I	Note 2
	Cardiac Adult							
Cardiac	Cardiac Adult, TEE							<del></del> .
Cardiae	Cardiac Pediatric, TEE		]					
	Cardiac Neonatal, TEE							
1	Cardiac, Pediatric							
ļ.	Cardiac, Neonatal							
Į.	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vascular							
Vessel	Other (Specify)							<del></del>

P= Previously cleared K072285

Combined: Note I: B/M, B/PWD, M/CD, B/CD/PWD

System: Prosound Alpha 7 Ver. 6.0

Transducer: UST-9132 I/T

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

<u> </u>	Clinical Application	1	в от т			ode of Operat	<del></del>	
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic	1 -	1	İ				
	Fetal	1	1					
1	Abdominal							
	Intra-operative (Specify)	Е	Е	Е	T	E	Note 1	-
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric		ļ .					
Fetal Imaging	Small Organ (Specify)	E	Е	E		Ē	Note I	
& Other	Neonatal Cephalic	1						
	Adult Cephalic							
	Trans-rectal	<u> </u>						
	Trans-vaginal							
	Trans-urethral	ļ						
	Trans-esoph. (non-Card.)		[					
	Musculo-skeletal (Convent.)						,	<del> </del>
j	Musculo-skeletal (Superfical)	ļļ						
	Other: Gynecological							
į	Cardiac Adult							
Condition	Cardiac Adult, TEE							
Cardiac	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
ļ	Cardiac, Pediatric							
	Cardiac, Neonatal							
1	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vascular	E	Е	E		E	Note I	
Vessel	Other (Specify)							

E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

Applications:- Intra-operative- (liver, pancreas, gall bladder, ....), Small Organ- (breast, testes, thyroid....).

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System: <u>Prosound Alpha 7 Ver. 6.0</u> Transducer: UST-9133

	Intended Use: Diagnostic ultrasoun Clinical Application	T				ode of Operat		<del></del>
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic	1		<del>                                     </del>	<del>-</del> -	<u> </u>		
-	Fetal	1		·			<del>                                     </del>	
	Abdominal	Е	E	E ·		Е	Note i	
	Intra-operative (Specify)	Ē	Е	E		E	Note I	
	Intra-operative (Neuro), Burr Hole			-				
	Inter-operative, Laparoscopic							
	Pediatric							
Fetal Imaging	Small Organ (Specify)							
& Other	Neonatal Cephalic							
	Adult Cephalic							<u>.</u>
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
ł	Musculo-skeletal (Convent.)					-		
ļ	Musculo-skeletal (Superfical)							
	Other: Gynecological			7				
	Cardiac Adult							
[	Cardiac Adult, TEE							
Cardiac	Cardiac Pediatric, TEE							
(	Cardiac Neonatal, TEE						1	
	Cardiac, Pediatric						<del></del>	
	Cardiac, Neonatal						-	· · · · · · · · · · · · · · · · · · ·
Ĺ	Intra-cardiac							
	Other (Specify)							
	Peripheral vascular							·
Vessel	Other (Specify)							

E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Applications:- Intra-operative- (liver, pancreas, gall bladder, ....)

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System: <u>Prosound Alpha 7 Ver. 6.0</u> Transducer: UST-9135P

	Intended Use: Diagnostic ultrasour Clinical Application			-		de of Operat		
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic	1						
	Fetal	E	Е	E		E	Note I	<u> </u>
	Abdominal	E	Е	E	-	E	Note 1	<del></del> .
	Intra-operative (Specify)							····
	Intra-operative (Neuro), Burr Hole	1						
	Inter-operative, Laparoscopic	<u></u>						
	Pediatric							
Fetal Imaging	Small Organ (Specify)							
& Other	Neonatal Cephalic			-				
	Adult Cephalic	<u>]</u>						
	Trans-rectal							
	Trans-vaginal						<u></u> .	
	Trans-urethral							
	Trans-esoph. (non-Card.)	ļ						***
1	Musculo-skeletal (Convent.)						_	
	Musculo-skeletal (Superfical)							·
	Other: Gynecological	Е	E	E		E	Note I	
	Cardiac Adult							
0- 25	Cardiac Adult, TEE							
Cardiac	Cardiac Pediatric, TEE			[				
<u> </u>	Cardiac Neonatal, TEE							
<u> </u>	Cardiac, Pediatric		_					
	Cardiac, Neonatal							<del></del>
ĺ	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vascular							
Vessel	Other (Specify)							

E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

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System: Prosound Alpha 7 Ver. 6.0

Transducer: UST-9136U

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	1				ode of Operat		
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
	Fetal	E	Е	E		E	Note 1	· -
	Abdominal	Е	E	Е		E	Note I	
	Intra-operative (Specify)	<u> </u>						
	Intra-operative (Neuro), Burr Hole	1				-		
	Inter-operative, Laparoscopic							
	Pediatric							
Fetal Imaging	Small Organ (Specify)	E	Е	E		E	Note I	
& Other	Neonatal Cephalic							·
	Adult Cephalic							
	Trans-rectal ·							
	Trans-vaginal							•
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other: Gynecological	E	E	Е		Ē	Note I	
í	Cardiac Adult							•
Cardiac	Cardiac Adult, TEE							
Cardiac	Cardiac Pediatric, TEE							
1	Cardiac Neonatal, TEE					- 1		
<u> </u>	Cardiac, Pediatric							
ļ.	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
F	Peripheral vascular							
Vessel	Other (Specify)							

E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

System: <u>Prosound Alpha 7 Ver. 6.0</u> Transducer: UST-9146 I/T

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application					ode of Operat		A****
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							<del></del>
	Fetal							
	Abdominal							
l	Intra-operative (Specify)	E	E	E		Е	Note 1	•
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric				-			
Fetal Imaging	Small Organ (Specify)							
& Other	Neonatal Cephalic					,		•
	Adult Cephalic							<del></del>
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)	1						
•	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other: Gynecological							· · · · · ·
	Cardiac Adult				_	-		•
	Cardiac Adult, TEE							
Cardiac	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
į.	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vascular							
Vessel	Other (Specify)							

E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Applications:- Intra-operative- (liver, pancreas, gall bladder, ....)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

resumption osc (Fer 21 Crit 601.107)

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-52101

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	1				ode of Operat		
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic						<del>                                     </del>	
	Fetal	1	1					
	Abdominal	1						
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
Fetal Imaging	Small Organ (Specify)	ľ						
& Other	Neonatal Cephalic							
	Adult Cephalic							
i	Trans-rectal					-		
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)					-		
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other: Gynecological					· f		
	Cardiac Adult	P	P	P		P	Note I	Note 2
	Cardiac Adult, TEE							
Cardiac	Cardiac Pediatric, TEE							
[	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vascular							
Vessel	Other (Specify)							

P= Previously cleared K072285

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

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System: Prosound Alpha 7 Ver. 6.0 Transducer: UST-52105

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body

	Clinical Application				M	ode of Opera	tion	
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic	<del>                                     </del>					<del>                                     </del>	
	Fetal			1			1	
	Abdominal							
	Intra-operative (Specify)							-
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic	I -						
	Pediatric					· · · · · · · · · · · · · · · · · · ·		
Fetal Imaging	Small Organ (Specify)							
& Other	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)					-		
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							-
	Other: Gynecological							
	Cardiac Adult	Ė	Е	E	Ē	Е	Note I	Note 2
	Cardiac Adult, TEE							
Cardiac	Cardiac Pediatric, TEE	1						
1	Cardiac Neonatal, TEE		•					
	Cardiac, Pediatric							
[	Cardiac, Neonatal							
[	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vascular			<del>-  </del>				
Vessel	Other (Specify)							

E = ndded to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

Applications:- Intra-operative- (liver, pancreas, gall bladder, ....), Small Organ- (breast, testes, thyroid....).

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System: Prosound Alpha 7 Ver. 6.0 Transducer: UST-52108

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

,	Clinical Application	Ī				ode of Operat	<del></del>	
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic					<del></del>		
	Fetal	Ì						
	Abdominal							
	Intra-operative (Specify)		<u> </u>					
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
Fetal Imaging	Small Organ (Specify)							
& Other	Neonatal Cephalic		<u>l                                     </u>					
	Adult Cephalic	<u> </u>	<u></u>					
	Trans-rectal							
	Trans-vaginal					,		
	Trans-urethral					i		
	Trans-esoph. (non-Card.)	L						
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)		[					
	Other: Gynecological							
	Cardiac Adult							
o de la constantina	Cardiac Adult, TEE							
Cardiac	Cardiac Pediatric, TEE							
i	Cardiac Neonatal, TEE							
1	Cardiac, Pediatric	N	N	N	N	N	Note I	Note 2
].	Cardiac, Neonatal	N	N	N	N	N	Note 1	Note 2
Ļ	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vascular							
Vessel	Other (Specify)		i			1	1	

N = new indication for system; P= Previously cleared K032875

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

Applications:- Intra-operative- (liver, pancreas, gall bladder, ....), Small Organ- (breast, testes, thyroid....).

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System: <u>Prosound Alpha 7 Ver. 6.0</u> Transducer: UST-52109

_Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as fo	Mower

Clinical Application			Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)			
Ophthalmic	Ophthalmic	1				•		<del></del>			
" " "	Fetal										
	Abdominal	1									
	Intra-operative (Specify)										
	Intra-operative (Neuro), Burr Hole							· · · ·			
	Inter-operative, Laparoscopic	N	N	N		. N	Note 1				
	Pediatric										
Fetal Imaging	Small Organ (Specify)		_								
& Other	Neonatal Cephalic							<del></del>			
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)		Ï								
	Musculo-skeletal (Convent.)						·				
	Musculo-skeletal (Superfical)										
	Other: Gynecological										
	Cardiac Adult										
[	Cardiac Adult, TEE		<u> </u>								
Cardiac	Cardiac Pediatric, TEE										
ĺ	Cardiac Neonatal, TEE										
	Cardiac, Pediatric										
	Cardiac, Neonatal										
[	Intra-cardiac						<del></del>				
	Other (Specify)							· · · · · · · · · · · · · · · · · · ·			
Peripheral	Peripheral vascular							<del>- · · · · · · · · · · · · · · · · · · ·</del>			
Vessel	Other (Specify)										

N = new indication for system; P= Previously cleared-K032875

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Applications:- Intra-operative- (liver, pancreas, gall bladder, ....)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

System: Prosound Alpha 7 Ver. 6.0

Transducer: UST-52110S

intended Use: Diagnostic ditrasound	imaging or fluid flow analysis of the human body as follows:
Clinical Application	34 1 60

Clinical Application			Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)			
Ophthalmic	Ophthalmic	1				·					
	Fetal	7	1								
	Abdominal										
	Intra-operative (Specify)	1	1					_			
	Intra-operative (Neuro), Burr Hole	T									
	Inter-operative, Laparoscopic										
	Pediatric										
Fetal Imaging	Small Organ (Specify)	}									
& Other	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skeletal (Convent.)										
	Musculo-skeletal (Superfical)										
	Other: Gynecological										
i	Cardiac Adult	i									
	Cardiac Adult, TEE							<del>-</del> '			
Cardiac	Cardiac Pediatric, TEE	N	N	N	N	N	Note 1	Note 2			
]	Cardiac Neonatal, TEE	N	N	N	N	N	Note 1	Note 2			
	Cardiac, Pediatric	[									
	Cardiac, Neonatal			ŀ							
	Intra-cardiac										
	Other (Specify)										
Peripheral	Peripheral vascular										
Vessel	Other (Specify)										

N = new indication for system;

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD, Note 2: B/CWD, B/CD/CWD

System: Prosound Alpha 7 Ver. 6.0

Transducer: UST-52114P

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application			d imaging or fluid flow analysis of the human body as follows:  Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)				
Ophthalmic	Ophthalmic			, ·								
	Fetal	1										
	Abdominal											
	Intra-operative (Specify)											
	Intra-operative (Neuro), Burr Hole	N	N	N		· N	Note 1					
	Inter-operative, Laparoscopic											
	Pediatric											
Fetal Imaging	Small Organ (Specify)											
& Other	Neonatal Cephalic											
	Adult Cephalic											
	Trans-rectal			ŀ								
	Trans-vaginal											
	Trans-urethral											
	Trans-esoph. (non-Card.)											
	Musculo-skeletal (Convent.)											
	Musculo-skeletal (Superfical)											
	Other: Gynecological					ĺ						
	Cardiac Adult											
o	Cardiac Adult, TEE											
Cardiac	Cardiac Pediatric, TEE											
	Cardiac Neonatal, TEE											
	Cardiac, Pediatric											
ļ	Cardiac, Neonatal											
į	Intra-cardiac			[								
	Other (Specify)											
Peripheral	Peripheral vascular											
Vessel	Other (Specify)					1						

N = new indication for system

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

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System: Prosound Alpha 7 Ver. 6.0

Transducer: UST-52119S

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)			
Ophthalmic	Ophthalmic										
	Fetal										
	Abdominal	1									
·	Intra-operative (Specify)										
•	Intra-operative (Neuro), Burr Hole										
	Inter-operative, Laparoscopic										
	Pediatric										
Fetal Imaging	Small Organ (Specify)				7	i					
& Other	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skeletal (Convent.)										
	Musculo-skeletal (Superfical)										
	Other: Gynecological										
	Cardiac Adult										
(	Cardiac Adult, TEE										
Cardiac	Cardiac Pediatric, TEE	N	N	N	N	N	Note 1	Note 2			
[	Cardiac Neonatal, TEE										
1	Cardiac, Pediatric										
	Cardiac, Neonatal										
	Intra-cardiac										
	Other (Specify)										
Peripheral	Peripheral vascular										
Vessel	Other (Specify)										

N = new indication for system, P= Previously cleared-K110207

Combined: Note I: B/M, B/PWD, M/CD, B/CD/PWD, Note 2: B/CWD, B/CD/CWD

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System: <u>Prosound Alpha 7 Ver. 6.0</u> Transducer: UST-52120S

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)			
Ophthalmic	Ophthalmic	1				<del></del>					
	Fetal Abdominal Intra-operative (Specify) Intra-operative (Neuro), Burr Hole										
	Inter-operative, Laparoscopic Pediatric			,							
Fetal Imaging & Other	Small Organ (Specify) Neonatal Cephalic										
	Adult Cephalic Trans-rectal										
	Trans-vaginal	<u> </u>									
	Trans-urethral										
•	Trans-esoph. (non-Card.)	-									
	Musculo-skeletal (Convent.)										
	Musculo-skeletal (Superfical) Other: Gynecological										
	Cardiac Adult							<u> </u>			
	Cardiac Adult, TEE										
Cardiac	Cardiac Pediatric, TEE										
	Cardiac Neonatal, TEE										
- 1	Cardiac, Pediatric										
ı	Cardiac, Neonatal	N	N	N		N	Note 1	Note 2			
ļ	Intra-cardiac										
	Other (Specify)							-			
Peripheral Vessel	Peripheral vascular										
A 62261	Other (Specify)	<u>.                                      </u>			- 1	į					

N = new indication for system; P= Previously cleared K032875, E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD, Note: 2: B/CWD, B/CD/CWD

System: Prosound Alpha 7 Vcr. 6.0

Transducer: UST-52121S

	Clinical Application			nd imaging or fluid flow analysis of the human body as follows:  Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)				
Ophthalmic	Ophthalmic	1	<u> </u>				1					
·	Fetal	<del> </del>	1									
	Abdominal	Î.										
	Intra-operative (Specify)											
	Intra-operative (Neuro), Burr Hole											
	Inter-operative, Laparoscopic	T										
	Pediatric											
Fetal Imaging	Small Organ (Specify)											
& Other	Neonatal Cephalic											
	Adult Cephalic	Ι				·						
	Trans-rectal	1										
	Trans-vaginal	1										
	Trans-urethral											
	Trans-esoph. (non-Card.)											
İ	Musculo-skeletal (Convent.)											
	Musculo-skeletal (Superfical)											
	Other: Gynecological											
	Cardiae Adult											
	Cardiac Adult, TEE											
Cardiac	Cardiac Pediatric, TEE											
1	Cardiac Neonatal, TEE											
l	Cardiac, Pediatric											
	Cardiac, Neonatal	N	N	N		·N	Note I	Note 2				
Ĺ	Intra-cardiac											
	Other (Specify)											
Peripheral	Peripheral vascular											
Vessel	Other (Specify)	T										

N = new indication for system; P= Previously cleared K110207, E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M,  $\,$  B/PWD, M/CD, B/CD/PWD  $\,$  , Note 2: B/CWD, B/CD/CWD  $\,$ 

System: Prosound Alpha 7 Ver. 6.0 Transducer: UST-52124

Clinical Application			nd imaging or fluid flow analysis of the human body as follows:  Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PW D	CWD	Color Doppler	Combined (Specify)	Other (Specify)			
Ophthalmic	Ophthalmic	1	<del>                                     </del>	<del>                                     </del>	<del>                                     </del>	<del></del> -	<del> </del>				
	Fetal	1	1	† <u> </u>			<del>                                     </del>				
	Abdominal	1	<u> </u>				1				
	Intra-operative (Specify)	1									
•	Intra-operative (Neuro), Burr Hole	1				<del></del> -					
	Inter-operative, Laparoscopic						-				
	Pediatric						<del> </del>				
Fetal Imaging	Small Organ (Specify)					<del></del>		<del></del>			
& Other	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skeletal (Convent.)				- <del></del>			<del></del>			
	Musculo-skeletal (Superfical)										
	Other: Gynecological							·-····································			
]	Cardiac Adult										
	Cardiac Adult, TEE			-				·			
Cardiac	Cardiac Pediatric, TEE										
Ĺ	Cardiac Neonatal, TEE										
-	Cardiac, Pediatric	N	N	N		N	Note I	Note 2			
	Cardiac, Neonatal			•							
<u>į</u>	Intra-cardiac		1			_	<del></del>	·			
	Other (Specify)							<del>_</del>			
Peripheral	Peripheral vascular										
Vessel	Other (Specify)										

N = new indication for system; P= Previously cleared K110207,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

510(k) # K122537

(Division Sign-Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

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